

**5. 510(k) SUMMARY**

September 24, 2009

**OWNER:**

FEB 17 2010

Baxter Healthcare Corporation  
One Baxter Parkway  
Deerfield, Illinois 60015

**CONTACT PERSON:**

Diane Rennpferd  
Manager, Global Regulatory Affairs  
1620 Waukegan Road  
McGaw Park, IL 60085  
Telephone: (847) 473-6293  
Fax: (847) 785-5116

**DEVICE NAME:**

**Trade name:**  
Xenium XPM

**Table 5-1.**  
**Product Codes for Xenium XPM**

M25649A	Xenium XPM 110
M25650A	Xenium XPM 130
M25651A	Xenium XPM 150
M25652A	Xenium XPM 170
M25653A	Xenium XPM 190
M25654A	Xenium XPM 210

**Common name:** Hemodialyzer

**Classification name:** Dialyzer, high permeability with or without sealed dialysate system

**PREDICATE DEVICE:**

**Table 5-2.**  
**Previous 510(k)s**

Device	Company	Previous 510(k)	Clearance date
Xenium XPH	Baxter Healthcare Corporation	K083778	February 20, 2009

**DESCRIPTION OF THE DEVICE:**

Xenium XPM dialyzers are Polyethersulfone fiber dialyzers and will be labeled for single use only. The dialyzers are available in six (6) sizes, which are differentiated by membrane surface area.

**STATEMENT OF INTENDED USE:**

Hemodialysis with Xenium XPM dialyzers is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

**TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:**

The Xenium XPM is substantially equivalent to Baxter's current legally marketed Xenium XPH dialyzer cleared February 20, 2009 (K083778).

**DISCUSSION OF NONCLINICAL TESTS:**

Baxter Healthcare Corporation conducts risk analyses, per ISO 14971, and design verification tests based on the result of these analyses. All test results meet the acceptance criteria, and support that the devices are appropriately designed for their intended use.

**CONCLUSION:**

The Xenium XPM is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G60  
Silver Spring, MD 20993-0002

Ms. Diane Rennpferd  
Manager, Global Regulatory Affairs  
Baxter Health Care Corporation  
Renal Division  
1620 Waukegan Road  
MCGAW PARK IL 60085

FEB 17 2010

Re: K093120  
Trade/Device Name: Xenium XPM  
Regulation Number: 21 CFR §876.5860  
Regulation Name: High permeability hemodialysis system  
Regulatory Class: II  
Product Code: KDI  
Dated: January 11, 2010  
Received: January 19, 2010

Dear Ms. Rennpferd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

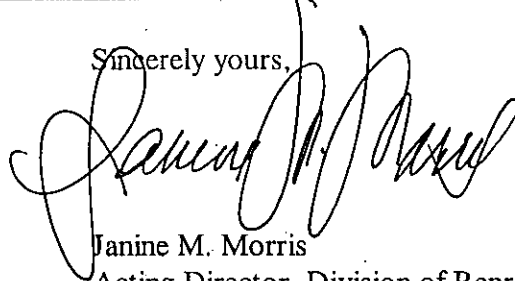
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name.

Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): K093120

**Device Name:**

Xenium XPM

**Indications for Use:**

Hemodialysis with Xenium XPM dialyzers is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.


Prescription Use   X   AND/OR Over-The-Counter Use           

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal and  
Radiological Devices  
510(k) Number K093120